

STATEMENT OF CONSIDERATIONS

REQUEST BY THE UNIVERSITY OF CHICAGO
AS OPERATOR OF ARGONNE NATIONAL LABORATORY
UNDER U.S. DEPARTMENT OF ENERGY CONTRACT NO. W-31-109-ENG-38
FOR A BLANKET ADVANCE WAIVER OF DOMESTIC AND FOREIGN RIGHTS
OF THE ENGELHARDT INSTITUTE OF MOLECULAR BIOLOGY, MOSCOW, RUSSIA
UNDER SUBCONTRACT NO. ANL-943352403 W(A)-95-012, CH-0860

The proposed Argonne National Laboratory (ANL) subcontract to Engelhardt Institute (Engelhardt) is directed to developing methods to assist in the determination of genome structure. Specifically, it will be directed toward a collaboration between ANL, which has developed an approach for economical, rapid, high volume DNA sequencing, referred to as Sequencing by Hybridization, and Engelhardt, which has developed a technique called Sequencing by Hybridization on Microchip (SHOM). The proposed project is multiyear and is projected to involve DOE funding to ANL at a level of \$1.6 million per year of which ANL will subcontract \$350,000 per year to Engelhardt.

ANL and Engelhardt will provide appropriate and complementary multi-disciplinary scientific and engineering staff to conduct further development of the SHOM technique. This concept was initially devised by the staff at Engelhardt and is presently at a proof-of-principle stage. It is anticipated that efforts by the Institute under the subcontract and by ANL will further the development and proof of this Sequencing by Hybridization technique. It is further anticipated that ANL will enter into a CRADA with a private industrial company, Affymetrix of Santa Clara, CA, which has been working and collaborating with the Engelhardt Institute.


As is pointed out in the petition for waiver, it is the intent of this waiver request to follow the model of the Department of Energy for implementation of PL 103-87 with the Institutes of the New Independent States of the Former Soviet Union. Pursuant to such, the University of Chicago, as ANL, would take title to inventions made by Engelhardt as well as those made by employees of ANL. Such disposition of rights permits packaging of the entire technology being developed with respect to Sequencing by Hybridization. It is further intended that ANL will share royalties with Engelhardt on a 50/50 basis of net royalties regardless of the source of the intellectual property. Such sharing of royalties while ANL administers the intellectual property and is responsible for processing the patent applications on inventions arising from the work is in parallel with other arrangements with Institutes of the New Independent States.

The waiver of rights to ANL will facilitate ANL's transfer of the developed technology to the private sector. It is fully anticipated that ANL will enter into a CRADA with Affymetrix, negotiations on such a CRADA being presently ongoing. The packaging of the technology will permit ANL to reach agreement with Affymetrix with respect to transfer into the private sector and commercialization of the entire technology package.

As is pointed out in the waiver petition, it is not believed that granting the requested waiver will have an adverse effect on competition or market concentration since ANL is subject to the terms and conditions of the Prime Contract including provisions reflecting Public Law 101-189 which governs its technology transfer activities.


Grant of the waiver will permit ANL and Engelhardt to establish an agreement which parallels the disposition of intellectual property under other interactions with the New Independent States. Further, ANL and Engelhardt have reached agreement on and will include in the subcontract, provisions whereby Engelhardt assigns to ANL underlying patent applications presently on file in the Patent Cooperation Treaty Office. ANL will take over prosecution and file the corresponding U.S. applications on these underlying inventions. These inventions likewise will be rolled into the package of technology further enhancing the commercializability of the technology.

Upon evaluation of the waiver petition in view of the objectives and considerations set forth in DOE PR 9-9.109-6 all of which have been considered, it is recommended that the requested waiver be granted. The scope of this waiver applies to the proposed ANL subcontract to Engelhardt and includes any extensions or amendments further pursuing the Hybridization by Sequencing project jointly being pursued by the two laboratories.

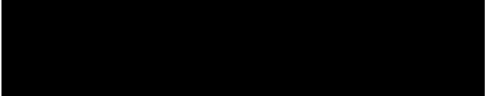

Robert J. Fisher
Acting Deputy Chief Counsel
Intellectual Property Law Division

Date: April 21, 1995

Based on the forgoing Statement of Considerations and the representations in the waiver request and accompanying material, it is determined that the interest of the United States and the general public would best be served by a waiver of the patent rights of the scope described above, and therefore the waiver is granted. The waiver shall not apply to a modification or extension of the contract where, through such modification or extension, the purpose, scope, or cost of the contract has been substantially altered, other than as indicated above with respect to extensions under this same program.


David A. Smith, Director
Health Effects and Life Science
Research Division
Office of Health and Environmental Research
Office of Energy Research

Date: May 3, 1995


Paul A. Gottlieb
Assistant General Counsel
for Technology Transfer and
Intellectual Property

Date: 5-4-95

WAIVER ACTION - ABSTRACT

W(A)-95-012 - CH-0860

REQUESTOR

Engelhardt Institute
(Argonne National
Laboratory)

CONTRACT SCOPE OF WORK

Development of technique for
sequencing by Hybridization

RATIONALE FOR DECISION

Engelhardt will assign inventions
to ANL and share 50/50 in royalties
made in all Engelhardt and ANL
inventions in the project.

DISPOSITION